K071682

AUG 15 2007

E. 510(k) Summary Statement

CRystalView T-Series Computed Radiography System

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

Submitter:	Alara, Inc. 47505 Seabridge Drive Fremont, CA 94538
Registration Number:	2953719
Contact Person:	Robert Lundberg Director of Regulatory Affairs and Quality Systems Phone: 510-315-5189 Fax: 510-315-5201
Date Prepared:	July 18, 2007
Trade Name:	CRystalView® T-Series Computed Radiography System
Common Name:	Computed Radiography (CR) System
Classification Name:	Solid State X-Ray Imager Class II, 21CFR 892.1650
Product Code:	90-MQB
Predicate Device:	K042023: Fuji Computed Radiography (FCR) ClearView CS Image Reader (CR-IR363) K955643: DenOptix ALARA Imaging System

Product Description:

The CRystalView T-Series System is an electrostatic X-ray imaging system that employs storage phosphor plates in place of conventional X-ray film for radiographic imaging applications. The system provides image data that must then be viewed with an external computer and appropriate software. The CRystalView T-Series System is comprised of the following functional components: Reusable storage phosphor plates, multiple sizes; Plate carousels, corresponding to reusable storage phosphor plate size; The CRystalView T-Series Scanner, an image reader /digitizer. The CRystalView T-Series Scanner / Communications Interface, USB 2.0; Optional Integrated phosphor plate eraser;

CRystalView T-Series control software and a user or distribution channel-supplied computer system. Image data is sent via a dedicated connection from the CRystalView T-Series Scanner to the computer system, where it is processed and displayed for review.

Indications for Use:

The CRystalView T-Series is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in general-purpose diagnostic procedures.

The CRystalView T-Series is not indicated for use in mammography.

Rationale for Substantial Equivalence:

The CRystalView T-Series is the equivalent of the DenOptix Imaging System. Its "Intended Use" statement limits the DenOptix Imaging System to dental computed radiography. The Fuji Computed Radiography (FCR) ClearView CS Image Reader uses the same ST-VI Imaging Plates for general computed radiography that is the same "Intended Use" desired for the CRystalView T-Series. Differences between the FCR ClearView and the present device are in the implementation of similar technologies for computed radiography. These differences do not alter the intended diagnostic effect of a computed radiographic imaging system.

Safety and Effectiveness Information:

The CRystalView T-Series is a Class II medical device and a Class I laser product. The CRystalView T-Series complies with applicable FDA and international standards pertaining to electrical, mechanical, EMC, and laser safety of medical and/or laser devices.

Alara's laboratory and V&V testing demonstrate that the CRystalView T-Series performance characteristics and diagnostic capabilities are equivalent to the predicate.

Conclusion:

The CRystalView T-Series' performance is substantially equivalent to the DenOptix Imaging System and the FCR ClearView using the ST-VI imaging plates.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Robert Lundberg
Director, Regulatory Affairs & Quality Systems
Alara, Inc.
47505 Seabridge Drive
FREMONT CA 94538

AUG 23 2013

Re: K071682
Trade/Device Name: CRystalView® T-Series Computed Radiography System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: July 18, 2007
Received: July 20, 2007

Dear Mr. Lundberg:

This letter corrects our substantially equivalent letter of August 15, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

C. Indications for Use Statement

510(k) Number: **K071682**

Device Name: CRystalView® T-Series Computed Radiography System

Indications for Use: The CRystalView T-Series is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in general-purpose diagnostic procedures.

The CRystalView T-Series is not indicated for use in mammography.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

8/15/07
(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K071682